6-28-04

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JUN 2 5 2004 E	IN THE UNITED STATES PATENT AND (Case No. 95,1408-SS	
In the state of th	ne Application of:	)
	Kellogg et al.	)
Seri	al No.: 10/602,564	) Examiner: )
Filir	ng Date: June 24, 2003	) Group Art Unit
For:	Devices and Methods for Using Centripetal Acceleration to Drive Fluid Movement in a Microfluidics System for Performing Biological Fluid Assays	) ) )

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. Copies of the references cited below are enclosed. These references are also listed on the enclosed PTO Form 1449.

In the judgment of the undersigned, portions of the listed references may be material to the Examiner's consideration of the presently pending claims. This statement is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103.

Applicants do not believe any fee is due with this submission. If this belief be in error and the Patent Office determines that the fee prescribed in the relevant portion of 37 C.F.R. Section 1.97 is applicable, the undersigned representative by his signature hereby authorizes any such fee to be debited from Deposit Account 13-2490.

Date: June 25, 2004

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff

Kevin E. Noonan Reg. No. 35,303



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 95,1408-SSS)

In the Application of:	)
Kellogg et al.	)
	) Examiner:
Serial No.: 10/602,564	)
	) Group Art Unit:
Filing Date: June 24, 2003	)
	)
For: Devices and Methods for Using Centripeta	1 )
Acceleration to Drive Fluid Movement in a	<b>)</b>
Microfluidics System for Performing Biolo	ogical )
Fluid Assays	)
TRANSMITT	<u>AL LETTER</u>

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In regard to the above identified application,

- 1. We are transmitting herewith the attached:
  - a) Information Disclosure Statement;
  - b) PTO Form 1449 and cited references;
  - c) Return postcard
- 2. With respect to fees:
  - a) No fees are required
  - b) Please charge any underpayment or credit any overpayment our Deposit Account, No. 13-2490. A duplicate copy of this letter is enclosed.
- 3. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1, are being deposited with the United States Postal Service with sufficient postage as Express Mail in an envelope addressed to the Commissioner for Patents, Alexandria, VA 22313-1450 on June 25, 2004.

Date: 25

25 June 2004

Respectfully submitted,

Kevin E. Noonan, Ph.D. Registration No. 35,303

Complete if Known tute for form 1449A/PTO Application No. 10/602,564 IN 25 2004 PORMATION DISCLOSURE 06-24-03 **Filing Date: First Named Inventor** Kellogg et al., TATEMENT BY APPLICANT Group Art Unit (use as many sheets as necessary) **Examiner Name** 95,1408-SSS 6 Attorney Docket No. Sheet

				U.S. PATENT DOCUMEN	TS	
Examiner	Cite	U.S. Patent	-	Name of Patentee or Applicant of	Date of Publication of Cited Document	Pages, Columns, Lines Where Relevant
Initials* No.	No. 1	Number	Kind Code <sup>2</sup> (if known)	Cited Document	MM-DD-YYYY	Passages or Figures Appear
	1	4,729,862		Salatiello et al.	July 21, 1981	
	2	4,381,291		Ekins et al.	April 26, 1983	
	3	4,515,889		Klose et al.	May 7, 1985	
	4	4,676,952		Edelmann et al.	June 30, 1997	
	5	4,745,072		Ekins	May 17, 1988	
	6	5,160,702		Kopf-Sill	November 3, 1992	
_	7	5,171,695		Ekins	December 15, 1992	
	8	5,173,262		Burtis et al.	December 22, 1992	
	9	5,242,803		Burtis et al.	September 7, 1993	
	10	5,409,665		Burd	April 25, 1995	
<u> </u>	11	5,413,732		Burd	May 9, 1995	
-	12	5,432,009		Tabata	July 11, 1995	
	13	5,472,603		Schembri	December 5, 1995	
	14	5,006,749		White	April 9, 1991	
	15	5,252,294		Kroy	October 12, 1993	
	16	5,304,487		Wilding	April 19, 1994	
	17	5,368,704		Madou	November 29, 1994	
	18	3,679,367		Negersmith	July 25, 1972	
	19	4,940,527		Kazlauskas et al.	July 10, 1990	
	20	4,515,889		Klose et al.	May 7, 1985	
	21	5,426,032		Phillips et al.	June 20, 1995	
	22	4,154,793		Guigan	May 15, 1979	

Examiner	Date
Signature	Considered

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to compete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC. 20231

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English translation is attached.

Substitute fo	or form 1449A/PTO			Complete if Known		
				Application No.	10/602,564	
	INFORMATION	DISCLOS	URE	Filing Date:	06-24-03	
	STATEMENT BY			First Named Inventor	Kellogg et al.,	
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(use as many sheets as necessary)				Examiner Name		
Sheet	2	of	6	Attorney Docket No.	95,1408-SSS	

				U.S. PATENT DOCUMEN	тѕ	<u> </u>
Examiner	Cite	U.S. Patent	Document		Date of Publication of	Pages, Columns, Lines
Initials*	No.	Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Figures Appear
	23	5,186,844		Burd	February 16, 1993	
	24	5,122,284		Braynin et al.	June 16, 1992	
	25	5,304,348		Burd et al.	April 19, 1994	
	26	5,457,053		Burd et al.	October 10, 1995	
	27	5,478,750		Berstein et al.	December 26, 1995	
	28	5,591,643		Schembri et al.	January 7, 1997	
	29	5,518,930		Burd et al.	May 21, 1996	
	30	5,474,603		Schembri et al.	December 5, 1997	
<u> </u>	31	5,693,233		Schembri	December 2, 1997	
	32	5,496,520		Kelton et al.	March 5,1996	
	33	5,061,381		Burd	October 29, 1991	
	34	5,242,606		Braynin et al.	September 7, 1993	
	35	5,403,415		Schembri	April 4, 1995	
	36	5,173,193		Schembri	December 22, 1992	
	37	5,275,016		Chatterjee et al.	January 4, 1994	
	38	5,624,597		Buhl et al.	April 29, 1997	
	39	5,599,411		Schembri	February 4, 1997	
	40	5,639,428		Cottingham	June 17, 1997	

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Examiner	Date	
Signature	Considered_	

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	41	5,622,819		Herman	04-22-1997	
	42	5,821,116		Herman	10-13-1998	
	43	4,030,834		Bauer et al.	06-21-1977	
	44	4,872,821		Weiss	10-10-1989	
	45	4,722,853		Batliwalla et al.	02-02-1988	
	46	4,258,740		Kaartinen et al.	03-31-1981	
	47	5,171,533		Fine et al.	12-15-1992	
	48	5,160,702		Kopf-Sill et al.,	11-03-1992	
	49	3,713,062		Butler et al.,	01-23-1973	
	50	3,952,116		Trenkler et al.	04-20-1976	
	51	5,590,052		Kopf-Sill et al.	12-31-1996	
	52	5,413,009		Fragnito et al.	05-09-1995	
	53	4,279,862		Bretaudiere et al.,	07-21-1981	
	54	6,302,134		Kellogg et al.	10-16-2001	
	55	6,063,589		Kellogg et al.	05-16-2000	
	56	6,399,361		Brotherston et al.	06-04-2002	
	57	3,528,449		White et al.	02-27-1968	
	58	4,612,959		Costello	09-23-1986	
	59	5,336,181		Nakao et al.	08-09-1994	
	60	5,431,303		Miskell	07-11-1995	

Examiner	Date	
Signature	Conside	red

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	61	wo	93/22053		Trustees of the University of PENN	11-11-1993		
	62	wo	93/22058		Trustees of the University of PENN	11-11-93		
	63	EP	417,305	A1	Idemitsu Petrochemical Co. Ltd.	3-20-1991		
	64	EP	616,218	A1	Hitachi, Ltd.	9-21-1994		
	65	EP	305,210		Biotrack, Inc.	12-81993		
	66	EP	322,657		Miles Inc.	7/5/89		
	67	GER	4,410,224		Gleich Anmelder	9/28/95		
	68	EP	647,367	B1	ABAXIS, Inc.	12/10/97		
	69	wo	95/33986		ABAXIS, Inc.	12/14/95		
	71	wo	97/08556		First Medical, Inc.	03-06-1997		
	72	EP	408 207		Illinois Tool Works Inc.	06-22-1990		
	73	wo	94/26414		Syntex Inc.	11-14-1994		
	74	UK	1 307 628		United Kingdom	08-21-1970		
	75	FR	1292407		France	03-24-1961		
	77	wo	97/21090		Gamera Bioscience	06-12-1997		

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		OTHER DOCUMENTS NON PATENT LITERATURE DO	CUMENTS					
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	78	78 Anderson, "Analytical Techniques for Cell Fractions" (1968), Anal. Biochem., 28: 545-562						
-	79	Aoki et al., "Electrochemical Response at Microarray Electrodes in Flo Determination of Catecholamines", (1990), Anal. Chem., 62: 2206-22		and and				
	80	Arquint et al., "Micromachined Analyzers on a Silicon Chip", (Septemb Vol. 40, No. 9, pp. 1805-1809.	per 1994), Clinio	cal Chemistry,				
	81	Ballantine et al., "Surface Acoustic Wave", (June 1989), Anal. Chem.,	61/11: pp. 704	-715.				
	82	Bertrand et al., "A One-Step Determiniation of Serum 5'-nucleotidase (1982), Clinica Chimica Acta, 119: 275-284.	using a centrifu	ulgal Analyzer",				
	83	Blackburn et al., "Electrochemiluminescence Detection for Development Probe Assays for Clinical Diagnostics", (1991), Clin. Chem., 37/9: 153	ent of Immunoa 34-1539.	assays and DNA				
	84	Bor Fuh et al., "Isolation of Human Blood Cells, Platelets, and Plasma Proteins by Centrifugal SPLITT Fractionation", (1995), Biotechnol. Prog., 11: 14-20.						
	85	Burtis et al., "Optimization and Analytical Application of the Technique of Dynamic Introduction of Liquids into Centrifugal Analyzers", (1974), Clin. Chem., 20: 932-941.						
-	86	Burtis et al., "Development of a Multipurpose Optical System for Use with a Centrifugal Fast Analyzer", (1975), Clin. Chem., 21/9: 1225-1233.						
	87	Cho et al., "Development of a Multichannel Electrochemical Centrifugal Analyzer" (1982), Clin. Chem., 28/9: 1961-1965.						
	88	Collison et al., "Chemical Sensors for Bedside Monitoring of Critically III Patients" (April 1990), Anal. Chem., 62/7: pp. 425-437.						
,	89	Columbus et al., "Architextured" Fluid Management of Biological Liquids", (1987), Clin. Chem., 33/9: 1531-1537.						
	90	Dessy, "Waveguides as Chemical Sensors", (October 1989), Anal. Chem., 61/19: 1079-1094.						
-	91	Ekins et al., "Multianalyte Microspot Immunoassay. The microanalytical 'compact disk' of the future", (1992), Ann. Biol. Clin., 50: 337-353.						
Examine Signatur			Date Considered					

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		OTHER DOCUMENTS NON PATENT LITERATURE DO	CUMENTS						
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	92	Esashi et al., "Anodic Bonding for Integrated Capacitive Sensors" (July 1992), Proc. Micro. Electro Mechanical Systems, 11: 43-48.							
	93	Foucault, "Countercurrent Chromatography" (1991), Anal. Chem., 63:							
	94	Fritsche et al., "Enzymatic Endpoint Analysis of Glucose with the Hexokinase Method and the Union Carbide Fast Centrifugal Analyzer", (1975), Clin Biochem., 8: 240-246.							
	95 Glass et al., "Effect of Numerical aperture on signal level in cylindrical waveguide evanescent fluorosensors" (June 1987), Appl. Optics, 26/11: 2181-2187								
	96	Haab et al., "Single Molecule Fluorescnece Burst Detection of DNA Fragments Separated by Capillary Electrophoresis" Anal. Chem., 1995, 67, 3253-3260.							
	97	Hadjiioannou et al., "Automated Enzymic Determination of Ethanol in Blood, Serum, and Urine with a Miniature Centrifugal Analyzer", (1976), Clin. Chem. 22/6:802-805.							
	98	Heineman, "Biosensors Based on Polymer Networks Formed by Gamma Irradiation Crosslinking", (1993), App. Biochem. Biotech., 41: 87-97.							
	99	Ikada, "Surface Modification of Polymers for Medical Applications", (1994), Biomaterials, 15/10: 725-736.							
	100	Lamture et al., "Direct Detectoin of Nucleic Acid Hybridization on the Surface of a Charge Coupled Device", (1994), Nucleic Acids Res., 22/11: 2121-2125.							
	101	Lee et al., "Automated System for Fractionation of Blood Samples" (1978), Clin. Chem., 24/8: 1361-1365.							
	102	Linliu et al., "Development of a Centrifuge Ball Viscometer for Polymer Melts", (1994), Rev. Sci. Instrum., 65/12: 3823-3828.							
	103	Nakagawa et al., "A Micro Chemical Analyzing System Integrated on a Silicon Wafer", Proc. IEEE Workshop of Micro Electro Mechanical Systems, pp.89.							
	104	Poole et al., "Instrumental Thin-Layer Chromatography", (January 19937A.	94), Anal. Chen	m., 66/1: 27A-					
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	105	Reijenga et al., "Effect of Electroosmosis on Detection in Isotachophoresis",(1983), J. Chromatography, 260: 241-254.					
	106	Renoe et al., "A Versatile Minidisc Module for a Centrifugal Analyzer" (1974), Clain. Chem., 20/8:955-960.					
	107	Rosenzweig et al., "Laser-Based Particle-Counting Microimmunoassay for the Analysis of Single Human Erythorcytes" (1994), Anal. Chem., 66: 1771-1776					
	108	Schembri et al., "Portable Simultaneous Multiple Analyte Whole-Blood Analyzer for Point-of-Care Testing" (1992), Clin. Chem., 38/9: 1665-1670					
	109	Shoji & Esashi, "Micro flow cell for blood gas analysis realizing very small sample volume" (1992), Sensors and Actuators, B8: 205-208.					
	110	Wilding et al., "Manipulation and Flow of Biological Fluids in Straight Channels Micromachined in Silicon" (1994), Automat. Analyt. Tech., 40: 43-47.					

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